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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/574,398 | 03/31/2006 | Ian Taylor | 5176 | 7428 |

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| EXAMINER | |
|---|---|
| BABIC, CHRISTOPHER M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1637 | |

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/574,398 | TAYLOR ET AL. | |
| | Examiner | Art Unit | |
| | Christopher M. Babic | 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, drawn to method for providing a patient diagnosis for lung cancer.

Group II, claim(s) 4-6, drawn to method for distinguishing between normal and disease tissues.

Group III, claim(s) 7-12, drawn to method to monitor the response of a patient being treated for lung cancer by administering a anti-cancer agent and a method for identifying a compound useful for the treatment of lung cancer.

Group IV, claim(s) 13, drawn to a oligomer array for distinguishing between normal and disease tissues.

Group V, claim(s) 14, drawn to a polypeptide array for distinguishing between normal and disease tissues.

The inventions listed as groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An array comprising two or more probes corresponding to two or more genes listed within claim 13 was known in the art at the time of invention (Brennan, U.S. 5,474,796). Brennan teaches the formation of all possible permutations of the 10-mer oligonucleotide (col. 9, ex. 4, for example).

The said method cannot therefore be considered a special technical feature, as lack of unity rules hold that a feature known to a person of ordinary skill in the art makes no advance over the prior art.

2. This application further contains claims directed to the following patentably distinct combination of sequences.

Groups I-VI

Each combination of SEQ ID NOs comprises patentably distinct combination of sequences.

Each combination is patentably distinct because they comprise a group of unrelated sequences, and a further restriction is applied to the group. For an elected group, Applicants must further elect a **single** combination of nucleotide sequence. For example, Applicants must elect a single combination (i.e., 20, 100, 200 or 366 genes) of genes and identify the genes of the combination in the claims. Applicant is further

advised to select a combination of sequences that include any sequences Applicant believes to be free of the prior art. If one elected sequence is found to be allowable, any permutation of combination comprising the SEQ ID NO would be allowable.

The above restriction practice is supported by MPEP 803.04, example (c), wherein the section states:

"Applications containing only composition claims reciting different combination of individual nucleotide sequences...**will be** subject to a restriction requirement. Applicants **will be** required to select **one combination** for examination. If the selected combination contains **ten or fewer sequences, all of the sequences of the combination will be searched**. If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth above for example (B)"

Example (B) states that the presence of one novel and nonobivious sequence within the

combination will render the entire combination free of prior art (MPEP 803.04).

Therefore, Applicants must elect a **single combination** of polynucleotide (or gene) sequences to which the claimed combination comprises. Further, Applicants are advised to identify the sequences (or genes) (within the combination) which are least likely to be found in the prior art, for the examination to be facilitated.

3. This application further contains claims directed to the following patentably distinct Restriction Subgroups of the claimed invention. After election of one of the Groups above, Applicant is required to also elect a restriction subgroup. This is not a

species election. Applicant will be required to cancel non-elected subject matter upon indication of allowable subject matter.

Groups I-IV

The probe array (e.g. claim 2) and polypeptide array (e.g. claim 3) each comprise a patentably distinct subgroup.

The probe array (e.g. claim 2) and polypeptide array (e.g. claim 3) do not share a special technical feature because the structures of polynucleotide and polypeptides are different and thus there is no unity of invention between the two groups.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed Subgroup consisting of a method utilizing **either** a probe array or polypeptide array for prosecution on the merits to which the claims shall be restricted.

Applicant is advised that a reply to this requirement must include an identification of the restriction subgroup that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Should applicant traverse on the ground that the Restriction Subgroups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the Restriction Subgroups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised

that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/30/06

Christopher Babic
Patent Examiner
AU 1637

YOUNG J. KIM
PRIMARY EXAMINER
12-11-06